# 510(k) Summary of Safety and Effectiveness

for

# Radionics Software Applications, Inc.

XKnife-4

K981055

# 1. SUBMITTER

Radionics Software Applications, Inc. 22 Terry Avenue
Burlington, MA 01803 USA

Contact Person:

Lisa Misterka Benati

Senior Regulatory Engineer

#### 2. NAME OF DEVICE

Device Proprietary Name:

XKnife-4

Device Common Name:

Radiation Treatment Planning System

## 3. DEVICE CLASSIFICATION

Class II: 21 CFR 892.5900 X-ray Radiation Therapy System

#### 4. DEVICE INTENDED USE

XKnife-4 is intended for use in stereotactic, collimated beam, computer planned, LINAC (linear accelerator) based radiosurgery and radiotherapy treatment.

## 5. PREDICATE DEVICES

- Radionics Software Applications, Inc. XKnife-3 System
- Radionics Software Applications, Inc. XPlan-1 System

#### 6. GENERAL SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and user quality assurance procedures. The training and

installation sessions provide assurance that the user understands all aspects of the XKnife-4 System: mechanical, computer and software, plus its intended functionality. This information promotes safe and effective use of the device.

#### 7. COMPARISON OF TECHNICAL CHARACTERISTICS

The XKnife-4 system has similar technical characteristics as the commercially available XKnife-3 system. Both systems consist of treatment planning software, stereotactic hardware and a protocol of extensive verification and QA procedures to ensure proper transfer of the treatment parameters to the clinical delivery system. The XKnife-4 system also has similar technical characteristics as the commercially available XPlan-1 system. Both systems support the use of the LINAC jaws, in addition to a circular collimator, to further shape the radiation beam.

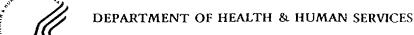
# 8. NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The design of the XKnife-4 system, including the use of the LINAC jaws, has been thoroughly validated at the unit and system level. Nonclinical tests were conducted to demonstrate that the XKnife-4 software meets all product requirements. This testing also demonstrates that the performance is substantially equivalent to the predicate devices cited above.

Radionics Software Applications, Inc. XKnife-4 510(k)

3/19/98

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Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Lisa Misterka Benati Senior Regulatory Engineer Radionics Software Applications, Inc. 22 Terry Avenue Burlington, MA 01803 Re: K981055

XKnife-4 Stereoactic RTP System

Dated: July 13, 1998 Received: July 14, 1998 Regulatory class: II

21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Benati:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.

Director, Division of Reproductive Abdominal, Ear, Nose and Throat

and Radiological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Prescription Use	510(k) Number	Oevices K98/055  OR  3/19/98	Over-The-Counter Use  (Optional Format 1
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